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No. 04-1084

In The
Supreme Court of the United States

ALBERTO R. GONZALES,
ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

O CENTRO ESPIRITA BENEFICIENTE
UNIAO DO VEGETAL, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit

BRIEF OF ROBERT GABLE, Ed.D., Ph.D., HARRIET DE WIT, Ph.D., WAYNE HALL, Ph.D., CHRIS-ELLYN JOHANSON, Ph.D., WILLIAM A. MCKIM, Ph.D., DANIEL M. PERRINE, Ph.D., AND MANUEL TANCER, M.D., AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici are a group of scientists and policy experts who have extensive clinical experience and scholarly expertise regarding drug abuse and drug control policy.

- Robert S. Gable, Ed.D., Ph.D., is Professor of Psychology (Emeritus) at Claremont Graduate University.
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[1] Pursuant to Rule 37.6, *amici curiae* certify that no counsel for a party authored this brief in whole or in part. This brief was written by counsel for *amici*. No person or entity other than *amici curiae* and their counsel made any monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.2(a), the parties have consented to the filing of the brief of *amici curiae* and their letters of consent accompany this brief.

- Manuel Tancer, M.D., is Chairman of the Department of Psychiatry and Behavioral Neurosciences at Wayne State University School of Medicine.[2]

Although *amici* represent a wide range of political perspectives and opinions about organized religion, *amici* all agree that a careful analysis of the actual empirical data admitted in the record in this case regarding drug use for religious purposes will serve the public interest.

SUMMARY OF ARGUMENT

The district court found, and the court of appeals affirmed, that Petitioners failed to meet their burden under the Religious Freedom Restoration Act[3] (RFRA) of proving a compelling interest in banning O Centro Espirita Beneficiente Uniao do Vegetal's (UDV) sacramental use of *hoasca*. Petitioners continue to assert that the government has a compelling interest in banning the sacramental use of *hoasca* because it poses 1) a serious health risk to the members of UDV and 2) a significant risk of diversion of *hoasca* to non-religious uses. Petitioners make these assertions, however, without conducting the kind of prudent assessment that a clear understanding of chemical substances and drug control policy requires. Petitioners' reliance upon general policy statements and newly produced, non-record evidence does a great disservice not only to this Court and UDV, but to the pursuit of a just and scientifically-grounded drug control policy.

[2] More complete biographies of *amici* are provided in the Appendix of this brief.

[3] 42 U.S.C. § 2000bb, *et seq*.

The record reveals that UDV's sacramental use of *hoasca* poses neither serious health risks to its members nor any significant potential for diversion to non-religious uses. Factually speaking, on the record of the district court, this is not a difficult case. First, the record supports the district court's finding that the government failed to prove that UDV's use of *hoasca* is likely to cause cardiological or psychological problems. Second, the record also supports the district court's finding that the government failed to prove that *hoasca* has been, or is likely to be, diverted to non-religious use.

As scientists and public policy experts our goal was to evaluate the evidence in the record "in its entirety" in an objective and scholarly manner. *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985). *Our candid and measured tone should not be interpreted as a lack of confidence or be used to obscure our ultimate conclusion: a substantial preponderance of the evidence in the record supports the church.*

ARGUMENT

THE DISTRICT COURT'S FINDING THAT THE GOVERNMENT FAILED TO PROVE A COMPELLING INTEREST WAS NOT CLEARLY ERRONEOUS.

RFRA requires a fact-intensive review of the government's asserted interest in applying the Controlled Substances Act to UDV's sacramental use of *hoasca*. 42 U.S.C. § 2000bb-1(b). The government cannot justify its ban by resort to general policy statements regarding generic

categories of drugs, or by reference to the use of substances in contexts that are so dissimilar to UDV's sacramental use of *hoasca* as to render such references of no assistance. A thoughtful, scientific review of the evidence in the record leaves no doubt that UDV's sacramental use of *hoasca* poses no serious health risks to UDV members. Also, the record presents little, if any, credible evidence that permitting sacramental use of *hoasca* will lead to the diversion of *hoasca* to illicit, non-religious uses.

A. The Record Amply Supports The District Court's Finding That The Government Failed To Prove That The Sacramental Use Of *Hoasca* Poses A Serious Health Risk To UDV Members.

No drug or chemical is risk-free: all risk must be placed in perspective. Some degree of health risk is involved in virtually all human activity, whether drinking liquids (such as grapefruit juice), taking medicine (such as aspirin), or participating in religious rituals (such as circumcision). J.A. 804-05, 810-12. The government cannot establish a compelling interest sufficient to prohibit a sincere religious ceremony by merely showing that there may be *some* risk from the consumption of *hoasca*. The imposition of such a minimal burden would render RFRA meaningless. Instead, RFRA demands that the government prove a *compelling* interest – an interest "of the highest order" – to justify burdening UDV's religious practices. *See Wisconsin v. Yoder*, 406 U.S. 205, 215 (1972) (using standard incorporated by RFRA at 42 U.S.C. § 2000bb(b)(1)).

Given the demands of RFRA and scientific inquiry, it is important to be precise about the manner in which UDV

members prepare *hoasca* and the manner in which they consume it. Both procedures contribute to and limit the ultimate physiological and psychological effects of the substance. The *hoasca* tea used by UDV members is prepared by boiling the leaves from the plant *Psychotria viridis* and the bark from the vine stem of *Banisteriopsis caapi* for several hours. J.A. 22.[4] It is presently believed that when the DMT (N,N-dimethyltryptamine) in *Psychotria* is mixed with harmala alkaloids in *Banisteriopsis*, the resulting mixture allows orally administered DMT to become psychologically active. J.A. 343. The question, then, is whether the government established at the preliminary injunction stage that this particular preparation, consumed orally in the context of UDV ceremonies, presents serious health risks to UDV members.

Petitioners claim UDV's sacramental use of *hoasca* endangers its members' health. However, there is no scientifically significant evidence in the record supporting this claim. There is certainly not enough evidence to conclude that the district court abused its discretion and clearly erred in finding that the government failed to meet its burden under RFRA. FED. R. CIV. PRO. 52(a) ("[f]indings of fact . . . shall not be set aside unless clearly erroneous"); *Ashcroft v. A.C.L.U.*, 124 S.Ct. 2783, 2790 (2004) (preliminary injunction reviewed for abuse of discretion).

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[4] Citations to the parties' Joint Appendix are referred to herein as "J.A. ___."

1. Consumption of *hoasca* does not cause an increase in the occurrence of cardiac irregularities.

a. There is no scientific evidence of significant cardiac impairment of UDV members.

Though the government claims that use of *hoasca* causes cardiac irregularities,[5] the evidence to which the government points is not scientifically significant. The studies cited by the government in support of this claim found no irregularities corresponding to heart disease. J.A. 721-22.

Another preliminary study of fifteen long-term UDV members during a *hoasca* session showed an initial mild elevation of heart rate and blood pressure, followed by a gradual return to baseline. J.A. 302. While there is no valid way of generalizing the results of this preliminary study to the whole population of UDV members, the cardiac performance of long-term *hoasca* drinkers resembles that of the normal, general population. J.A. 287. In fact, the government's own expert confirmed that there was no evidence that allowed him to say to a reasonable degree of scientific certainty that there are cardiac irregularities associated with the use of *hoasca*. J.A. 797. *Amici* believe that his statement accurately reflects the present state of scientific knowledge.

The fact that DMT is chemically related to LSD and psilocybin, which the government cites as evidence of *hoasca*'s risk to UDV members,[6] is actually evidence of the

[5] Pet. Br. at 33.

[6] Pet. Br. at 32.

opposite. J.A. 778. The periodic use of LSD-like hallucinogens is generally considered to be "very safe" in terms of being non-injurious to major organ systems. J.A. 855. There are no known fatalities associated with *hoasca* within UDV, and there are no recorded overdose deaths in the medical literature from use of DMT. J.A. 832, 855, 884.

b. UDV takes appropriate and effective precautions against drug interactions.

Petitioners assert a compelling interest in banning UDV's sacramental use of *hoasca* because of a danger of interaction with other substances.[7] The record does show that the MAO-inhibiting beta-carbolines in *hoasca* may interact adversely with certain prescription drugs (such as Prozac, Zoloft, Paxil) or over-the-counter medications (such as St. John's Wort and pseudoephedrine) resulting in "serotonin syndrome." J.A. 127-28. The syndrome is characterized, in part, by hyperthermia, fluctuation of vital signs, tremor, and agitation. J.A. 128.

However, UDV deals with drug interactions the same way that medical personnel deal with them: they inform their members of the dangers and ask whether they are taking any other substances. J.A. 680, 694. The record shows that serotonin syndrome rarely occurs when medical patients are informed of potential drug interactions. J.A. 800. UDV does exactly this. J.A. 680, 694. Furthermore, church physicians and leaders interview all potential participants to rule out the presence of other

[7] Pet. Br. at 34.

medications (MAO inhibitors and SSRI medications) that might induce adverse interactions. J.A. 295, 694.

Additionally, the interview by church officials of new members asks about health problems and hospitalizations. J.A. 694. While legitimate questions can be raised about the effectiveness of the church's reporting and screening process (particularly self-reporting procedures[8]), we can reasonably assume that the screening process catches some proportion of vulnerable individuals. There is no record evidence that the church has had a drug-interaction serotonin syndrome among its eight-thousand Brazilian members. J.A. 308.

2. The UDV's sacramental use of *hoasca* does not cause psychological or social dysfunction.

The evidence does not support the government's claim that *hoasca* contributes to and causes psychosis, in spite of the evidence that the hallucinogenic effect of *hoasca* has the potential to worsen pre-existing psychosis or to precipitate an adverse psychological reaction by producing frightening experiences. J.A. 182, 253, 713-14. Although oral DMT alters perceptions and cognitions, the user does not lose connection to reality. J.A. 291, 778. The ceremonial participants are almost always aware of their surroundings and able to speak coherently. J.A. 291. Participants are not disoriented. J.A. 778. Many walk to the restroom as a result of diarrhea, and they would presumably be able to respond to an emergency. J.A. 294, 471, 653. The hallucinogenic experience spontaneously

[8] J.A. 788.

resolves in three to four hours, and participants return to their normal state of consciousness. J.A. 291, 654. At the end of the ceremony, participants engage in singing and group discussion. J.A. 61.

The government claims that *hoasca* has caused twenty-four psychotic incidents in Brazil over a period of five to six years.[9] A review of the entire record, however, reveals that only eight to thirteen arguably psychotic incidents have been documented during ceremonies, J.A. 624, 685, 691-92, and many or most of these psychological problems were transient in nature and resolved. J.A. 623, 714.

It is in fact reasonable to conclude, on the basis of a preliminary study of fifteen long-term tea drinkers, that some participants will experience psychological *improvements* such as increased self-confidence and acceptance of others. J.A. 93, 301. If the improvement percentage were substantial, we would expect to find that church members would have *fewer* incidents of psychosis than the general population, but this does not appear not to be the case, as UDV's experience is similar to that of the general population. J.A. 789. On the other hand, the rate of psychotic episodes might be as low as only 13 incidents out of 250,000 *hoasca* servings consumed. J.A. 699, 701.

UDV takes precautions against what dangers there may be from *hoasca* in two ways: pre-screening and

[9] Though the government states that twenty-four such incidents have been documented, Pet. Br. at 34, a review of the case histories in the record reveals that in many of those, either no truly psychotic incident was identified or no causal link to *hoasca* was found. J.A. 182-265.

controlling the amount in any given serving. First, the church has established guidelines to identify persons who might be vulnerable to mental health problems. J.A. 680, 694. Pre-ceremonial screening can reduce adverse reactions, but no screening procedure will catch all pre-existing vulnerabilities. The closed ceremonial setting, called the "vessel" by church members, itself reduces the impact of the hallucinogenic experience. J.A. 93.

A typical serving of approximately one-cup (200 ml) of *hoasca* contains 25 mg of DMT. J.A. 343. UDV members do not standardize their tea preparation with respect to the quantity of DMT or beta-carbolines due to the natural variability in DMT and alkaloid concentration in the plants. J.A. 124. The person conducting the ceremony drinks the tea before administering it to UDV members in order to test for potency. J.A. 578. Varying amounts of tea are initially offered to participants, and depending upon individual reactions, participants may be offered a second cup at their request. J.A. 580, 600. This is a traditional and sensible way to monitor potency as UDV administers its sacrament.

Critically, *petitioners' expert admitted that he had seen no evidence that social dysfunction arises from hoasca use*. J.A. 138. After examining all the data in the record related to this matter, we are left with one statistical estimate: the incidence of psychosis among the church members is approximately the same as in the general population. J.A. 700-01, 789.

3. *Hoasca* presents minimal dependence (addiction) potential.

The government did not prove, contrary to its claim, that *hoasca* presents significant potential for abuse.[10] A core issue in determining the dependence or abuse potential of a substance is whether its reported positive and euphoric effects lead to compulsive, repetitive dosing. J.A. 150. Euphoric effects, as measured by a standardized psychometric scale are much lower for DMT than for opiates, such as heroin. J.A. 319. While users of *hoasca* also report a positive experience on this scale, it is rarely the type of euphoria associated with drugs of abuse. J.A. 152, 757. For example, many users have reported sustained positive changes in mood and outlook as the result of the *hoasca* acting as a "catalyst." J.A. 93, 292.

A small controlled study of UDV participants found that they performed the same as normal control participants on a questionnaire measuring "reward dependence." J.A. 95. This "dependence" variable measures personality characteristics such as detachment and persistence. The results of this study indicate that *hoasca* consumption does not lead to compulsive use. Furthermore, only 15 to 20 percent of first-time participants in UDV ceremonies become UDV members. J.A. 700. This indicates that there is no strong tendency for people who experience *hoasca* for the first time (at least in the UDV environment) to repeat that experience in a compulsive manner.

A possible explanation for the affirmative attitude but non-compulsive behavior of *hoasca* consumers is that many of the positive aspects of ceremonial *hoasca* occur in

[10] Pet. Br. at 35.

the second part of the church service, after the drug effects have diminished, and ritual singing and group discussion take place. J.A. 60-61. Some of the benefits involve dramatic and positive lifestyle changes that come about days or months later. J.A. 93. Rituals, prayers, the source of the plant material, and other elements of worship are described as a part of a larger, disciplined routine. J.A. 182, 533. Participants have reported that the use of *hoasca* within the context of the UDV ritual structure is essential to positive outcomes, such as "being a good father" and discontinuing use of alcohol. J.A. 65, 93.

This attribution is consistent with what is known about the importance of a person's intention for using a particular drug and the social setting in which the experience takes place (commonly referred to as "set and setting" variables). J.A. 293. These are major factors in determining the nature of a hallucinogen-related experience. J.A. 645. To this extent, the positive reinforcing aspects of oral *hoasca* as used in a disciplined social setting should be clearly distinguished from the rapid onset of anxiety or euphoria that follows injected DMT, especially in less structured environments. J.A. 296, 342.

From a pharmacological perspective, the most reasonable assumption is that the abuse potential of DMT will be similar to LSD and other indolealkylamine hallucinogens such as psilocybin and bufotenine. J.A.153. Even in recreational use, these hallucinogens produce very little addiction and dependence. J.A. 339, 874. Furthermore, DMT-related hallucinogens, such as *hoasca*, are seldom listed in the scientific literature as drugs of abuse that activate brain reward pathways. J.A. 339. In short, the evidence in the record clearly reflects that *hoasca* does not lead to what we commonly know as "addiction."

B. The Record Amply Supports The District Court's Finding That The Government Failed To Prove That UDV's Sacramental Use Of *Hoasca* Would Lead To Significant Diversion To Non-Religious Use.

The record reflects no evidence of a danger of significant diversion of *hoasca* to non-religious use. In fact, the record shows quite the opposite.

1. There is no evidence that UDV has diverted its supplies to non-religious use.

There is no evidence in the record that UDV has diverted its supplies of *hoasca* to non-religious use. There is evidence that UDV has been less than forthright in declaring the contents of shipments of *hoasca* that they have imported from Brazil. J.A. 573, 897. This is a practice that *amici* believe should be corrected. However, there is no evidence that UDV diverted any of its *hoasca*, or offered it for sale, once it was inside the United States. J.A. 327. This may be evidence of the seriousness of attitude and the adequacy of controls instituted by UDV officials. J.A. 535-36. It may also be that the market for DMT is limited, particularly in liquid form, where hundreds or thousands of gallons of *hoasca* would have to be produced to be economically profitable. J.A. 356-57. Either way, there is no evidence of diversion of UDV's supplies of *hoasca*.

2. The physical discomfort of *hoasca* consumption makes diversion unlikely.

Though the government argues that interest in and use of DMT is rising, the record shows that *hoasca* is unlikely to become widely used or the next big "party

drug," in the government's words.[11] This is so in part because *hoasca* often induces gastrointestinal distress. J.A. 294. This helps prevent diversion, although the extent of this effect is debatable. J.A. 51. Obviously, substances that cause anxiety, nausea, vomiting, and diarrhea are not socially popular. People may be curious, experiment once, and then seek other substances with fewer or less intense side-effects.

Physically unpleasant substances simply do not make for good "party drugs." Peyote (mescaline) is another hallucinogen known to be physically unpleasant. J.A. 406. This characteristic, in addition to the United States government's modest control of harvesting and distribution, may account for the fact that there has been little, if any, increase in the illicit use of peyote or mescaline since the 1994 passage of the American Indian Religious Freedom Act amendments. J.A. 321, 753, 906. There is no evidence of diversion of peyote from the Native American Church itself. J.A. 917.

Contrast *hoasca* with MDMA (methylenedioxymethamphetamine), popularly known as "ecstasy," a well-known "party drug." The government has submitted evidence that MDMA has become a contemporary prototype drug for wide-spread abuse, particularly at "rave club" scenes. J.A. 162, 516. Amphetamines like MDMA are popular because they produce euphoric effects. J.A. 150-51, 873.

[11] Pet. Br. at 39.

However, as a government expert witness acknowledged, one does not find DMT, of any preparation, in rave clubs. J.A. 516. Instead of MDMA's euphoric effects, DMT sometimes produces frightening experiences. J.A. 581. This difference, particularly combined with the gastrointestinal distress it causes, make it unlikely that *hoasca* will ever become a "party drug" similar to MDMA.

Petitioners support much of their "party drug" diversion argument by reaching outside the record, citing to a number of publications of dubious scientific quality. For example, one such citation refers to DMT – not *hoasca* – as "The Lunch-Hour Psychedelic: A Thirty Minute Trip," without giving any indication of the contents of the article, the science behind the sensationalistic title, or even whether the article itself was published in the Australian *Daily Telegraph*, the *Idaho Statesman*, or *Psychopharmacology Update*. Pet. Br. at 40 n. 27. The government's approach is not supported either by the record or by basic principles of disciplined inquiry.

3. Illicit demand for DMT, if any, would more likely be met by domestic supplies than diversion from UDV's ceremonial use.

If public demand for DMT were to increase as the government suggests (a possibility for which there is no support in the record),[12] illicit producers would be more likely to produce it using readily available domestic plants

[12] Additionally, there is no evidence in the record that such a hypothetical increase in interest would be due to UDV's sacramental use of *hoasca*.

than imported *hoasca*.[13] J.A. 318, 320. Local production would be less expensive and would avoid the higher risk of detection inherent in importation. J.A. 326. Even if *hoasca* provided the same positive effects as other hallucinogens or stimulants, it would have less appeal in illegal drug traffic because an effective dose of *hoasca* (a 200 milliliter cup of liquid containing 25 milligrams of DMT) is much more difficult to clandestinely transport than a smaller quantity of dry material such as a postage stamp containing 100 micrograms of LSD or a tablet containing 125 milligrams of MDMA. J.A. 326, 334.

CONCLUSION

The trial court record overwhelmingly supports the district court's finding that the government failed to meet its burden of proving a compelling interest in banning UDV's sacramental use of *hoasca*. For each risk of which the government warns, the government cites to evidence that is substantially contradicted in the record, is empirically weak, or is simply irrelevant. *Amici* submit that the district court's findings were not clearly erroneous and

[13] Phalaris grass (containing DMT) and Syrian rue (containing beta-carbolines) are the best-known plant sources in the United States. J.A. 318, 320.

that the district court did not abuse its discretion in granting UDV's request for a preliminary injunction.

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William A. McKim, Ph.D. Professor of Psychology, Memorial University of Newfoundland. Dr. McKim, after receiving his doctorate in psychology from the University of Western Ontario, served as a Research Associate in the Laboratory of Psychobiology, Harvard Medical School. In recent years, he has served as an expert witness on drugs and alcohol in more than twenty cases in Canadian courts and has testified before the Parliament of Canada's House of Commons Committee on the Nonmedical Use of Drugs. His textbook, *Drugs and Behavior: An Introduction to Behavioral Pharmacology*, published by Prentice Hall, is now in its fifth edition.

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Mind-Altering Drugs: History, Pharmacology, Cultural Context, documents the pharmacological and psychological characteristics of virtually all known psychoactive substances. It was selected by the American Chemical Society as one of a series of scholarly volumes to be published by the Oxford University Press.

Manuel Tancer, M.D. Chair, Department of Psychiatry and Behavioral Neurosciences, Wayne State University School of Medicine. Dr. Tancer's department has 71 full-time faculty members and more than eleven million dollars in external research funding in areas such as brain imaging, substance abuse, and the developmental impact of drug or toxin exposure. Dr. Tancer earned his bachelor's degree from Princeton University and his medical degree from the University of Arizona College of Medicine. He was a featured speaker at the 2001 international conference on MDMA/Ecstasy sponsored by the National Institute on Drug Abuse.